DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

September 4, 2014

IMRIS, INC.
Ms. Karissa Holcomb
Regulatory Affairs Specialist
5101 Shady Oak Rd
Minnetonka, MN 55343

Re: K141950
Trade/Device Name: HFD100 Rocker Arm Accessory
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical head holder (skull clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: July 17, 2014
Received: July 18, 2014

Dear Ms. Holcomb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31,2017
See *PRA Statement below.*

510(k) Number *(if known)*
K141950

Device Name
Head Fixation Device (HFD100) Rocker Arm Accessory

Indications for Use *(Describe)*
The IMRIS Head Fixation Device System is an MR compatible mechanical support system which is used in head, neck and spine surgery when rigid fixation is required for cranial stabilization.

Type of Use *(Select one or both,* as *applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

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510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part §807.92.

Submitter: IMRIS, Inc.

5101 Shady Oak Road

Minnetonka, MN 55343

Establishment Registration Number: 3010326005

Contact Person: Karissa Holcomb BS, MS

Regulatory Affairs Specialist

Telephone: 763.203.6411

Fax: 866.992.3224

Email: kholcomb@imris.com

Alternate Contact Person: Daniel Biank, JD, MEng, PE, RAC

VP, Regulatory Affairs, Quality, & IT

Telephone: 763.203.6310

Fax: 866.992.3224

Email: dbiank@imris.com

Date Prepared: July 17, 2014

Device Name

Trade Name: Head Fixation Device (HFD100) Rocker Arm Accessory

Common Name: Neurosurgical Head Holder (Skull Clamp)

Classification Name: Neurosurgical head holder (skull clamp)

Predicate Devices:

510(k)	Decision Date	Device Name	Manufacturer
K103493	Mar. 03, 2011	Head Fixation Device (HFD100)	IMRIS, Inc.

Device Description:

The IMRIS Head Fixation Device System (HFD100) Rocker Arm Accessory is an MR compatible mechanical support system intended to use in head, neck and spine surgery when rigid fixation is required for cranial stabilization.

The HFD100 and its accessories are designed to immobilize the head during surgical procedures and support patient in the prone, supine or lateral positions. The HFD100 system is comprised of the table adapter, linkage system, one or two rocker arm skull clamps, and skull pins. The HFD100 system can be used with either the operating room table or the angiography room table. The table adaptor is used to mount HFD100 on the table. The linkage system is used to mount the Skull Clamp (including 3 or 4 skull pins) to the table Adapter. Please refer to Figure 1 for overview of the HFD100 and HFD100 Rocker Arm Accessory systems.

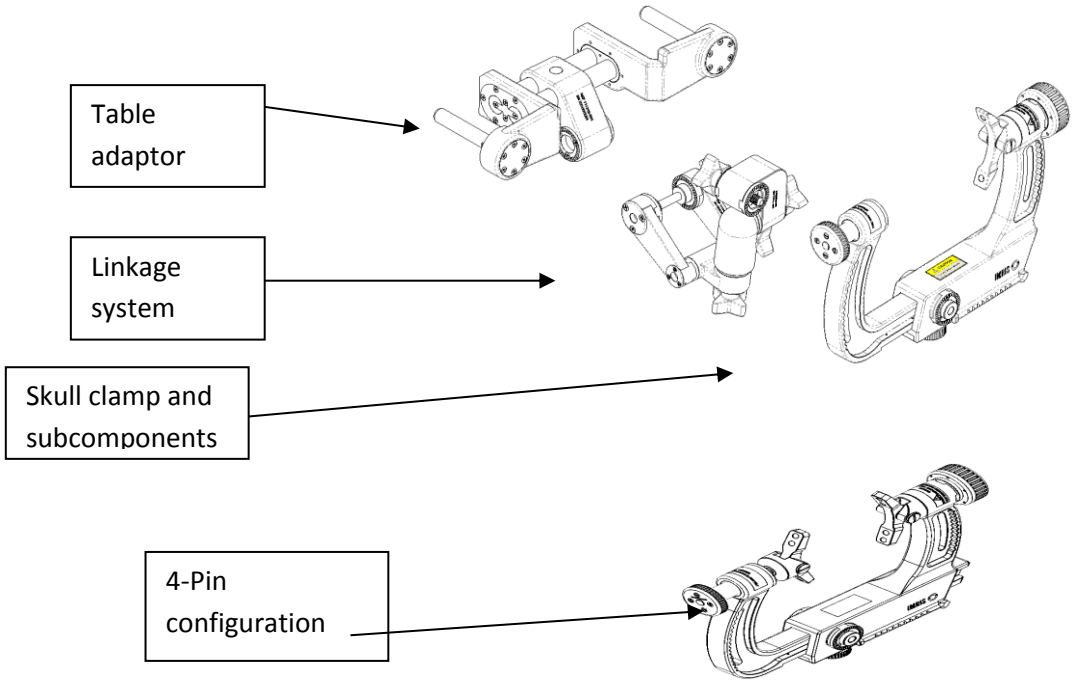

Figure 1 IMRIS HFD100 and HFD100 Rocker Arm Accessory

The Skull Clamp requires the use of three (3) or four (4) Skull Pins. IMRIS is using MAYFIELD® Disposable and Reusable Titanium Skull Pins manufactured by Integra LifeSciences Corporation and cleared by FDA K072208. The MAYFIELD® Disposable and Reusable Titanium Skull Pins are used in surgical procedures when rigid fixation is desired and Intra-Operative MR imaging is used. IMRIS and Integra LifeSciences Corporation have signed a supplier agreement to allow use of their titanium pins as a component of the IMRIS HFD100 system. Integra is responsible for the regulatory approvals of this product.

IMRIS 3-pin and 4-pin HFD100 attached to the OR table assembly is part of the IMRISneuro system. The linkage system is used to position the skull clamp in the necessary position, without colliding with the magnet bore. The HFD100 can be used individually or with the IMRIS Flexible Intra-operative Head Coils and third party accessories, such as retractor systems and navigation mounts. The HFD100 provides rigid skeletal fixation within the optimal imaging envelope while introducing minimal artifacts in the acquired images.

Figure 2 IMRIS Neuro System with HFD100 and OR table

The IMRISneuro 1.5T/3T Systems (Neuro II-SE/Neuro III-SV) are traditional MRI units that have been suspended on an overhead rail system to facilitate intra-operative, interventional and diagnostic use. The main components of the IMRISneuro systems are the MRI system, the magnet mover system, the OR Table assembly, the Intra-operative Coil and the Head Fixation Device. The IMRISneuro intra-operative imaging systems are tools for radiologists and surgeons, used to acquire images for diagnosis and surgical planning and monitoring during surgery. When images are requested by the surgeon, the magnet is brought into the operating room or Angiography room moving on a pair of overhead rails. The patient remains stationary throughout the procedure and the magnet moves into the room and over the patient for imaging. The magnet can be moved into and out of the surgical field multiple times, as required, throughout the course of the surgical procedure. The surgeon has access to updated MR

images in the surgical field, but does not have to change the way the surgery would typically be performed. Obtaining images intra-operatively allows surgeons to verify the absence of surgical complications before releasing the patient from the operating room. IMRIS 1.5T (Neuro II-SE) is cleared by K061916 and K071099 and IMRIS 3T (Neuro III-SV) is cleared by K093137 and K091166.

Intended Use:

The IMRIS Head Fixation Device Rocker Arm Accessory is an MR compatible mechanical support system which is used in head, neck and spine surgery when rigid fixation is required for cranial stabilization.

Comparison with Predicate Devices:

The IMRIS Head Fixation Device (HFD100) Rocker Arm Accessory is substantially equivalent to the currently cleared and marketed IMRIS HFD100 (K103493). The only design change to the current HFD100 is the addition of the Rocker Arm Accessory allowing the physician to choose between a 3-pin configuration and a 4-pin configuration.

The current HFD100 is an MR compatible mechanical support system which is used in head, neck and spine surgery when rigid fixation is required for cranial stabilization. It uses one rocker arm with 2 pins and stationary pin holder on the opposite side. The HFD100 Rocker Arm Accessory is also an MR compatible mechanical support system which is used in head, neck and spine surgery when rigid fixation is required for cranial stabilization, however, it allows the physician to choose the current 3-pin configuration of the HFD100 or they have the option to switch out the stationary pin holder for the Rocker Arm Accessory adding an additional pin to the configuration; distributing the weight evenly over all 4 pins. These differences have been identified and assessed in risk management and verification and validation testing.

Standards:

No product standards have been referenced within this submission.

Summary of Studies:

HFD100 Rocker Arm Accessory performance has been evaluated in verification and validation to ensure the 4-pin configuration maintains the performance of the 3-pin HFD100 system components.

HFD100 Rocker Arm Accessory verification and validation supports a determination of substantial equivalence.

Conclusion:

The IMRIS Head Fixation Device (HFD100) with the Rocker Arm Accessory is substantially equivalent to the currently cleared and marketed IMRIS HFD100 (K103493).